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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,437	03/02/2001	Thomas Charles Elleman	50179-086	9960

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EXAMINER

SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
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1631

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DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,437

Applicant(s)

ELLEMAN ET AL.

Examiner

Monika B Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 24-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 54-56 is/are rejected.
- 7) ☒ Claim(s) 9, 12 and 13 is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Amendment A

Applicants' arguments, filed 11 June 2002, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Election/Restrictions

As indicated in the previous office action mailed 11 March 2002, the restriction requirement is made final.

This application contains claims 24-53 drawn to an invention non-elected with traverse in Paper No. 7, filed 10 December 2001. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings Notice

Applicant is hereby reminded of the notification that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached to the back of the PTO-948 included in the office action mailed 09 November 2001, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Claim Rejections - 35 USC § 101

The rejection of claims 1-23 under 35 U.S.C. 101, has been overcome by the amendments to claims.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 and 54-56, as necessitated by amendment, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 is directed to a method of selecting a compound, however the specification does not provide basis for selecting a compound as per the steps in the instant claims. However the process of selection is described in relation to the identification of compounds of a particular structure as seen in Group II, claims 24-29; versus the design of a compound. Thus the method of selecting a compound is new subject matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 and 54-56, as necessitated by amendment, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained with respect to the amended claims 1-23 for reasons of record and newly applied to claims 54-56. Applicant has not presented any arguments to the following rejections of indefiniteness, thus they are reiterated from the previous office action mailed 11 March 2002. Any new rejections discussed below have been necessitated by amendment.

Claims 1-23 are vague and indefinite due to the lack of clarity in the claim language "designing or selecting" claim 1, line 1. The body of the claim lacks any active steps of design in addition to lacking any steps of selection. Applicant may intend step B to represent the step of selection, however obtaining a compound insinuates the completion of selecting one

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compound. Thus it is unclear what steps of methodology applicant looks to define as the active steps of design or selection, aside from the description or characterization of the desired compound. Claims 54-56 are also indefinite due to dependency from claim 1.

Claims 1-23 are indefinite for failing to recite a final process step that agrees back with the preamble. The preamble indicates a process of design or selecting. If a process of design is intended then the basic steps of ligand or molecular design must be recited in a positive, active fashion. If a process of selection is intended then the active steps of selection by discrimination from a collection of compounds must be present in some manner in order for the following steps of compound assessment to specific criterion to be met. For example, claim 1 is drawn to a method for designing a compound that binds to a molecule, yet the claim recites only the characterization of the molecule to which the binding of the designed compound occurs. As discussed in the previous office action indicated, the dependent claims continue only to describe that which occurs once the compound is designed, or now, selected. The claims lack an actual step that demonstrates the method of design or selection to produce a successful EGF-receptor binding compound as recited in the preamble; thus do not accomplish that which the preamble sets forth. As such claims 1-23 are rendered vague and indefinite. Claims 54-56 are also indefinite due to dependency from claim 1.

Claim 1 is vague and indefinite due to the lack of clarity of the claim language "obtaining a compound" in step (B). It is unclear if the compound intended is one other than that in the preamble or that in step (A). Claims 2-23 and 54-56 are also indefinite due to dependency from claim 1.

Claim 1 is vague and indefinite due to the lack of clarity of the term "obtaining" in step (B). It is unclear as to what are the metes and bounds of the parameters that define obtaining a compound. It is unclear if the compounds are obtained virtually, as by selection from screening a database, or by experimental assays. Claims 2-23 and 54-56 are also indefinite due to dependency from claim 1.

Claims 2 and 3 are vague and indefinite due to the lack of clarity of the term "complement". It is unclear what are the metes and bounds of the parameters that define the degree of complementarity required.

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Claims 54 and 46 are vague and indefinite due to the lack of clarity of the claim language "the testing in (v)" of line 1. It is confusing if applicant is pointing to a possible step of claim "(v)", because claim 1 does not have a step (v).

Claim Rejections - 35 USC § 103

The rejection of claims 1-23 under 35 U.S.C. 103 is hereby withdrawn due to the Garrett et al (*Nature*, July 1998) reference not preceding as appropriate the effective priority date of the instant application to the foreign application filed: May 29, 1998. In addition, the arguments were found to be persuasive.

Prior Art

The prior art does not teach the specific limitations of the modeled atomic coordinates of the EGF receptor as required by claims 1.

Claim Objection

Claims 9, 12 and 13 are objected to because of the following informalities: the term " – sheet" is missing the appropriate symbol " β " as recited in the original claims. Appropriate correction is required.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 8, 2002

Monika B. Sheinberg
Art Unit 1631

MB

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER